REMARKS

Claims 1-35 are pending and stand rejected as final. Applicants have canceled all 35 claims without prejudice or disclaimer in favor of new claims 36-71. Reconsideration of the rejection is respectfully requested.

Applicants thank the examiner for the courtesies extended during the telephonic interview on November 3, 2005.

To assist in the examiner's review of the claims, Applicants point out that claims 36 and 37 are focused as two-phased, as evidenced by the "consisting of" language. Further, new claim 38 is similar to former claim 34, but it clarifies that the ceramic granules are blended as an admixture, and that the consistency of the device is limited to that of a putty (and not also that of a paste). Further, new claim 39 is similar to former claim 30. Still further, new claim 43 is similar to former claim 1, except it now clarifies that the matrix is "fibers" and not merely "fibrous" in nature, and that the consistency of the device prior to implantation is that of a putty (and not alternately described as a paste).

Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter, specifically for the claimed "tissue conductive matrix". Applicants respectfully submit that the instant amendment to the specification renders this objection moot.

Claim Objections

Claims 1, 30 and 34 were objected to because of a number of informalities. Applicants respectfully submit that cancellation of these claims in favor of the new set of claims renders the objections moot.

Claim Rejections - 35 USC §112

Claims 30-34 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully submit that cancellation of these claims in favor of the new set of claims should render this rejection moot.

Claim Rejections - 35 USC §102

Claims 1-34 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication US2002/0183855 to Yamamoto et al. (hereinafter referred to as "Yamamoto"). Applicants respectfully traverse this rejection.

The Action stated that "the Yamamoto matrix comprises the same materials as Applicants' matrix, using the same ratios and consistency, and is intended for the same purpose(s). The results will inherently be the same." Applicants respectfully disagree with this statement.

In its most basic form, the claimed implant features non-soluble fibers and a flowable biocompatible polymer, thereby imparting to the implant, at least prior to implantation, a consistency of putty.

In a preferred embodiment, the claimed implant includes one or more additives, which may be a ceramic particle such as tricalcium phosphate. The ceramic particles are blended or admixed into the system of fibers and flowable polymer, and typically are held in place by the flowable biocompatible polymer, not by chemical bonding, ("mineralizing") as in Yamamoto. During the interview, Dr. Kronengold explained that Yamamoto uses very small particles, and these must be immobilized on the fibers lest they cause an inflammatory response in the body. Yamamoto immobilizes his small ceramic particles on collagen fibrils by a chemical bonding process called "mineralizing". In contrast, immobilization is not required in the present invention because the ceramic particles are much larger than in Yamamoto (100 microns versus 5 microns), and generally do not cause an inflammatory response. Moreover, and as the attached Declaration of co-inventor Dr. Russell Kronengold states (please refer to Appendix A), the terms "blended" and "mixed", as used in the present specification, exclude the kind of chemical bonding that is characteristic of the mineralizing of Yamamoto. Thus, the invention of independent claim 38 and its dependents is patentable over Yamamoto, Applicants respectfully submit.

In another preferred embodiment, and as claimed in independent claims 38 and 39 and their dependents, the invention features collagen fibers as the non-soluble fibers. Referring to Appendix B, which is another Declaration from Dr. Kronengold specifically discussing collagen chemistry and structure, Dr. Kronengold states that collagen can organize itself into structures of increasing complexity. In addition, Dr. Kronengold states that the term "collagen fibers" refers to that highest level of collagen structural organization, insoluble collagen made up of the organized collections of the smaller subunits of collagen, in cross-linked form. As such, it excludes the less complex, less organized, collagen units (i.e., tropocollagen or fibrils. Yamamoto uses the fibrillar form (i.e., fibrils) for his implant. This is because although he may use native sources such as animal tissue as his collagen source, his mineralization process requires exposure to low (less than 3) or to high (greater than 11) pH media, will break down any collagen fibers to the simpler subunits such as fibrils, or tropocollagen. Thus, the invention of independent claims 38 and 39 and their dependents are patentable over Yamamoto, Applicants respectfully submit.

Finally, an aspect of the claimed invention shared by all of the claims is that the implant, at least prior to implantation in the body of a living being, has the consistency or viscosity of a putty. As such, the claimed putty, does not exhibit a spring-back effect or "shape memory", but rather, remains in a deformed condition when it is subjected to a shearing stress. Referring again to Appendix A, the attached declaration of Dr. Kronengold confirms that the claimed "putty consistency" excludes the property of shape memory. Yamamoto requires that his implant possess shape memory (Paragraph [0031]). As such, the claimed invention, that is, each of claims 36-71 is patentable over Yamamoto, Applicants respectfully submit.

Further, Applicants respectfully submit that the slurry disclosed in Yamamoto does not anticipate the claimed invention because this is an intermediate material, and not Yamamoto's final implant product.

In summary, Yamamoto discloses a process which will yield a material consisting of soluble and fibril forms of collagen, which have very fine minerals chemically immobilized on their surface; whereas, the embodiments of the current invention which were discussed, comprise high-order collagen fibers, with relatively coarse ceramic particulate which is constrained mechanically by the physical size of the aforementioned fibers. The additional processing steps discussed regarding the present invention render the material in a putty-like state, and this state does not exhibit the shape memory required by Yamamoto.

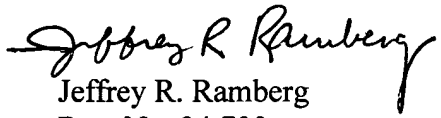
Still further, Applicants respectfully submit that new claims 36 and 37 are patentable over Yamamoto because Yamamoto does not meet the limitations of these two claims. Specifically, Yamamoto requires a mineral component, which is outside the scope of these "consisting of" claims.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In view of the above amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 36-71.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,



Jeffrey R. Ramberg
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November 22, 2005

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Appendix A

DECLARATION UNDER 37 CFR §1.132 OF CO-INVENTOR RUSSELL T. KRONENGOLD

I, Russell T. Kronengold, declare and say as follows:

That I am an inventor named on U.S. Patent Application Serial No. 10/713,438, entitled "Devices and Methods for Treating Defects in the Tissue of a Living Being";

That I am named as an inventor or co-inventor on 5 pending U.S. patent applications;

That my formal education consists of a Bachelor of Science degree in Chemical Engineering from Carnegie Mellon University, and a Master of Science in Biomedical Engineering from Rutgers University/University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, and a Doctor of Philosophy degree in Biomedical Engineering from Rutgers University/University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School;

That the above-identified patent application is subject to an obligation of assignment to Kensey Nash Corporation, a Delaware corporation with facilities in Exton, Pennsylvania;

That I am employed by Kensey Nash Corporation at its Exton facility as an engineer;

That I have 8 years experience in this position, and that I have 10 years experience overall as an engineer;

That I am familiar with the invention claimed in the above-identified patent application;

That, in one embodiment, the claimed implant may include one or more additive materials;

That, in a preferred embodiment, such as claimed in independent claim 38, an additive material may include ceramic bodies such as granules or chips;

That such ceramic bodies are blended or mixed with the fibers and flowable biocompatible polymer;

That there is no chemical treatment accompanying the blending or mixing of such ceramic bodies into the implant of the present invention, and that such blending or mixing is a physical admixing process;

That Yamamoto describes a "mineralizing" process whereby ceramic particles are "immobilized on the matrix" of collagen fibrils;

That this mineralizing involves an adhesion technique that is conducted in a reactor at controlled pH using aqueous solutions of calcium chloride and tribasic sodium phosphate;

That, as a result of chemical reaction, calcium phosphate mineral is deposited on collagen fibrils;

That, at least for purposes of the present invention, the claimed blending of ceramic bodies excludes the mineralizing process of Yamamoto;

That, the claimed blending therefore excludes the chemical adhesion characteristic of the minerals deposited on collagen fibrils of Yamamoto;

Further, that the invention as claimed always includes the characteristic that the inventive implant, at least prior to implantation, has the consistency or viscosity of a putty;

That, in terms of its deformation characteristics, the claimed putty behaves similarly to putties that are known in the art;

More specifically, that the claimed putty has the inherent property or characteristic of being shapeable, in the sense that it is easily deformed and once deformed to a new shape, will essentially remain in that new shape until further deformed;

Thus, at least for purposes of the present invention, the claimed putty can be considered as not possessing the property of shape memory, and can be considered to exclude such attribute; and

That I understand that all statements made herein (including statements made in the attachment documents) of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further, declarant sayeth not.

Russell T. Kronengold

Russell T. Kronengold

11/21/05

Date

Appendix B

DECLARATION UNDER 37 CFR §1.132 OF CO-INVENTOR RUSSELL T. KRONENGOLD

I, Russell T. Kronengold, declare and say as follows:

That I am an inventor named on U.S. Patent Application Serial No. 10/713,438, entitled "Devices and Methods for Treating Defects in the Tissue of a Living Being";

That I am named as an inventor or co-inventor on 5 pending U.S. patent applications;

That my formal education consists of a Bachelor of Science degree in Chemical Engineering from Carnegie Mellon University, and a Master of Science in Biomedical Engineering from Rutgers University/University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, and a Doctor of Philosophy degree in Biomedical Engineering from Rutgers University/University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School;

That the above-identified patent application is subject to an obligation of assignment to Kensey Nash Corporation, a Delaware corporation with facilities in Exton, Pennsylvania;

That I am employed by Kensey Nash Corporation at its Exton facility as an engineer;

That I have 8 years experience in this position, and that I have 10 years experience overall as an engineer, during this time my work efforts have focused on collagen processing;

That I am familiar with the invention claimed in the above-identified patent application;

That in particular I am familiar with collagen chemistry and it was a basis for my graduate studies;

That collagen is a chain-like protein commonly found in connective tissue in a living organism;

That a collagen molecule can be considered to be the three strands of polypeptide material that hydrogen bond to one another in a triple helix arrangement which may be referred to as "tropocollagen";

That as the polymerization reaction continues, multiple numbers of these triple helix formations self-assemble together to form a **fibril** of collagen;

That fibrils associate into bundles;

That higher multiples of fibril bundles having a diameter in the range of 1-50 microns are classified as collagen **fibers**;

That the collagen portion of all soft connective tissue has similar chemistry at the tropocollagen and collagen fibril level of structural organization;

That there is essentially no difference in arrangement or structural organization at the collagen fibril level of organization and below;

That such differences in arrangement or structure ("structural differentiation") is definitely occurring at the collagen fiber level of organization, and above;

That the structural differentiation is what gives rise to native properties of naturally occurring collagen tissue;

That "reconstituted collagen" refers to collagen in fibril or fibril-like form which has been synthetically de-polymerized and re-polymerized, ;

That "natural insoluble collagen" has a higher degree of polymerization than reconstituted collagen;

That "natural insoluble collagen" therefore has a higher degree of polymerization than collagen fibrils;

That, in natural tissues, a higher degree of polymerization beyond that of a collagen fibril means that the collagen is in the form of a fiber;

That "natural insoluble collagen" inherently contains collagen in fiber form;

That our terms "natural insoluble collagen" and "native insoluble collagen" are equivalent and may be used interchangeably;

That consequently our claimed "native insoluble collagen" inherently contains collagen at the fiber level of structural organization, or higher;

That the collagen fibers of our implant invention have the same structural organization as the collagen fibers in their original natural source tissue;

That as a consequence, our claimed "native insoluble collagen" still maintains at least some characteristics of the collagen tissue from which it was made;

That I have reviewed the document cited as prior art in the Final Office Action dated June 27, 2005;

That, in particular, I have thoroughly read and analyzed the disclosure in the cited U.S. Patent Application Publication No. 2002/0183855 to Yamamoto et al.;

That the Yamamoto invention is directed to a tissue repair matrix in which the matrix features mineralized fibrillar collagen, collagen derivative, or modified gelatin, bound with a binder;

That, when Yamamoto's tissue repair matrix includes collagen, the Yamamoto reference states that his source of collagen can be any convenient animal source;

That Yamamoto states that native collagen may be utilized in his invention;

That I have concluded that Yamamoto uses, or can use what we have defined as "native insoluble collagen", but only as a raw material or feedstock material for making his mineralized fibrillar form of collagen;

That any native insoluble collagen (i.e., collagen having at least the fiber level of organization) of Yamamoto is chemically processed to make "mineralized fibrillar collagen";

That as part of this chemical processing, Yamamoto always de-polymerizes collagen fibers and any higher organizational levels of collagen tissue into lower levels of structural organization, such as fibrils or even tropocollagen, prior to or during the mineralization process;

Specifically, that Yamamoto's step of reducing pH to 3 as he describes in his Paragraph [0018] depolymerizes the collagen fibers into collagen fibrils, and moreover, may further break up some collagen fibrils into soluble tropocollagen molecules;

Further, that Yamamoto's subsequent step of raising pH to 7 in his Paragraph [0019] causes any tropocollagen molecules that may be present to precipitate out of solution as tropocollagen or collagen fibrils;

That the fibrillar portion of the product of this precipitation step is similar to reconstituted collagen, that may be also referred to as self-assembled fibrils formed from tropocollagen;

That Yamamoto's reference to "fibrillar collagen" means collagen in the form of individual collagen *fibrils*, and excludes collagen in the form of *fibers*;

That Yamamoto mineralizes collagen in fibrillar form, and not in fiber form;

That Yamamoto's mineralized fibrillar collagen does not re-polymerize to form collagen fibers;

That I have concluded that Yamamoto's final product consisting of a tissue repair matrix does not contain any collagen still in native fiber form; and

That further I have concluded that Yamamoto's final product consisting of "mineralized fibrillar collagen" does not meet the express and implied definitions of "(native) collagen fibers" as claimed in independent claims 38 and 39;

That I understand that all statements made herein (including statements made in the attachment documents) of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further, declarant sayeth not.

Russell T. Kronengold

11/21/05
Date